



January 07, 2019

**Subject: Formaldehyde Risk Evaluation and Potential High Priority Designation by EPA's Toxic Substances Control Act Program**

Dear Formaldehyde Stakeholder;

In June 2016, Congress passed the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (LCSA) to reform the regulation of chemicals in commerce in the United States. The LCSA provides the U.S. Environmental Protection Agency (EPA) with expanded authority under the Toxic Substances Control Act (TSCA) to: (1) subject all new and existing chemicals to an EPA safety review; (2) focus on chemicals that are the highest priorities for full risk-based safety assessments; (3) require additional health and safety testing of chemicals; (4) make an affirmative safety determination on conditions of use associated with a chemical; and (5) identify and implement risk management options for any use determined to present an unreasonable risk.

**Background and Timeline for EPA TSCA Risk Evaluation**

Importantly, in January 2019, EPA is expected to announce the next 20 chemical substances that will undergo review by its TSCA risk evaluation program. Based on EPA's guidance for selecting chemicals for risk evaluation, formaldehyde is a prime candidate for selection by EPA as a high priority chemical in this next round of reviews due to its widespread use in the production of consumer products and its inclusion on EPA's TSCA work plan.

The risk evaluations conducted by EPA's TSCA program are comprehensive and can have significant cost and regulatory implications to manufacturers, importers and users of a chemical identified as a high priority for risk evaluation. The scope of a risk evaluation will include evaluation of the relevant hazards, exposures, and conditions of use for a chemical. While the TSCA risk evaluation process can span approximately three years, to be fully considered the scientific information needed for the risk evaluation will need to be submitted within the first year of the process.

Implications of a formaldehyde TSCA risk evaluation include requiring manufacturers and importers to equally share payment of the \$1.3 million fee for EPA to conduct the risk evaluation. Stakeholders will also be tasked with providing relevant scientific data to support the conduct of the risk evaluation and identifying relevant conditions of use to be considered for evaluation. If EPA designates formaldehyde for risk evaluation in January 2019, formaldehyde stakeholders will need to meet an aggressive timeline to initiate and complete any relevant scientific research to inform the risk evaluation no later than January 2020. It is imperative that formaldehyde stakeholders be actively involved in this process to ensure that EPA's formaldehyde risk



evaluation is based on the most relevant science and takes into consideration the formaldehyde regulations that have already been implemented to effectively manage potential exposures.

### **TSCA Risk Evaluation Consortium Formation**

The next several months will be a critical time for formaldehyde manufacturers, importers, users and formulators to understand the timeline and requirements of the TSCA risk evaluation process; coordinate and leverage financial resources to inform a formaldehyde risk evaluation; and collaborate to engage with EPA on its formaldehyde risk evaluation activities.

For years, several producers, suppliers and users of formaldehyde and formaldehyde products, as well as trade associations representing key formaldehyde applications, have organized as members of the American Chemistry Council (ACC) Formaldehyde Panel (the Panel) to conduct scientific research, regulatory and legislative advocacy, and educational outreach. The Panel has invested millions of dollars in conducting and communicating the science. The Panel's efforts have included scientific research evaluating potential associations between formaldehyde and cancers; quantifying thresholds for formaldehyde exposure; and understanding differences between formaldehyde found in the environment and formaldehyde produced by normal body processes. This work has provided critical information for regulatory and scientific policy decision-making in the U.S. and abroad.

In an effort to share costs and promote efficiency to address a pending TSCA risk evaluation, formaldehyde stakeholders are forming a consortium to collaborate on the development of comments, generate relevant data and meet with EPA to discuss the TSCA risk evaluation. The ACC Center for Chemical Safety Act Implementation will serve as the scientific, technical and advocacy hub for providing information and building the consortium to help formaldehyde stakeholders navigate the TSCA risk evaluation process. Under the TSCA process, chemical manufacturers, processors, importers and downstream users of a chemistry will have some opportunities to provide input to the EPA and may be subject to Agency requests for additional information. Given the implications of a TSCA risk evaluation for current and future emission standards, permit requirements and the overall use of formaldehyde, stakeholders must play an active role in the evaluation process and maximize all the opportunities to provide input to EPA.

### **February 2019 Consortium Information Meeting**

There are important areas that will directly inform EPA's risk evaluation, including the relevant science on formaldehyde human health risk and understanding potential human exposures for the conditions of use the Agency will focus on during its evaluation. We are scheduling an in-person meeting and webinar in Washington, DC on February 20, 2019 with potential consortium members to discuss the path-forward and next steps of the TSCA risk evaluation process and how that may impact formaldehyde use and regulation. Notably, the members of the consortium will outline the priority conditions of use it intends to focus on during its future engagement with EPA and identify the relevant science needed to inform EPA's evaluation. We strongly encourage you to join us in February to learn how your organization will be impacted, and what you can do to collaborate with other formaldehyde stakeholders to ensure that formaldehyde remains a sustainable chemistry for use in various product applications.



Please contact me directly by email ([kimberly\\_white@americanchemistry.com](mailto:kimberly_white@americanchemistry.com)) or by phone (202-249-6707) to register to participate in the upcoming meeting, learn more about ACC's Center for Chemical Safety Act Implementation and to discuss the formaldehyde TSCA risk evaluation consortium. I look forward to speaking with you.

Sincerely,

Kimberly Wise White, PhD  
American Chemistry Council (ACC)  
Senior Director, Chemical Products & Technology Division

